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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,022	12/10/1999	MING CHENG	38-21(15084)	9594

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/05/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/459,022

Applicant(s)

CHENG ET AL.

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Continued Prosecution Application***

1. The request filed on May 21, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/459,022 is acceptable and a CPA has been established. An action on the CPA follows.

***Status of the Claims***

2. Claims 1-16 are pending, new claim 17 has been added, and claims 1-17 are examined in the instant application. An initialed copy of Applicant's form 1449 is attached.

3. All rejections not discussed below have been withdrawn.

***Information Disclosure Statement***

4. Applicant's Information disclosure statement, paper number 10, filed August 6, 2001, has been entered.

***Claim Rejections - 35 USC § 112-second paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

- After step (a) of claim 1, an Agrobacterium-inoculated explant was produced. Step (b) should recite what to do with the Agrobacterium-inoculated explant, not with the Agrobacterium.
- Where did the "transformed cell line" come from?

In claims 6, 7, 8 and 9, "the moisture-limitation or removal period" lacks antecedent basis.

Clarification or correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

- while being enabling for adding 100–300 microliters of water during the coculturing step,

does not reasonably provide enablement for

- all conditions that decrease the weight of Agrobacterium inoculated explants.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's invention related to a rapid transformation and regeneration system for plants. In particular, the inventions relates to a plant tissue preparation system.

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The breadth of applicant's claims encompass all conditions known to decrease weight of an explant, with no upper limits on the amount of weight lost, including physical removal of plant tissue from the experiment.

Applicant shows adding water in an amount of 100-300 microliters, at the coculturing step, will result in increased number of Gus spots, indicative of increased transformation efficiency.

The state of the art indicates that it is unpredictable as to what methods of decreasing the weight of the explant would increase transformation efficiency. It is unpredictable what amount of water should be added to the coculturing medium to decrease the weight of the explant. In fact, Table 3 (p 21-22. specification) shows that only the 100-300 microliters water addition conditions increased transformation efficiency. When no water was added, the weight of the explant decreased, but no increase in transformation was observed. Furthermore, while the 100-300 microliters water addition condition increased the transformation efficiency, none of the water additions resulted in a 30-50% weight decrease of the explant as recited in the claims. The percent of weight decrease for those which showed increased transformation efficiency was 20.3-23.0%, significantly less than Applicant's claimed 30-50%. Applicant should note that when the explant was exposed to conditions which decreased weight by 34.8%, no increased transformation efficiency was observed conditions (Table 3).

Re the "time period of moisture removal": Applicant claims no limitation on this time period—it can be instantaneous or infinitely long. It is well known in the art that removal of moisture, especially rapid removal of moisture, can cause osmotic shock, which is deleterious, especially to plant cells (Biochemistry & Molecular Biology of Plants, Buchanan et al, eds, 2000, American Society of Plant Physiologists, Rockville, MD, p 1158). It is unpredictable that any time period would function as desired. Finding proper conditions would require a myriad of experiments and would impose undue burden on one of ordinary skill of the art. As evidence of the importance of this, applicant claims specified time periods in dependent claims 6, 7 and 8.

In view of the breadth of the claims (any plant, any conditions than decrease the weight to the explant, and any percentage weight reduction) and the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-10, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Uze, M, et al, Plant Science 130 (1997) pages 87-95 (published July 27, 1997).

Uze teaches a method for producing a fertile transgenic rice plant (pg 94, 1<sup>st</sup> full paragraph) comprising introducing one or more genetic components (p 88, last paragraph, & continuing to p 89), coculturing rice calli (p88 1<sup>st</sup> paragraph, and Table 3)) with Agrobacterium containing the genetic component (p 90, paragraph continued from p 89) under plasmolysis conditions (p 90, paragraph continued from p 89). Uze further teaches a precultured tissue (p 89, last paragraph) and use of a one day (p 90, paragraph continued from p 89) time period for plasmolysis, after inoculation with Agrobacterium. It should be noted that plasmolysis is caused by water loss from the plant cell (Webster's dictionary, p900).

Accordingly, Uze anticipates the claimed invention.

11. Claims 1-10, 12, and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hiei et al, Plant Journal (1994) 6: 271-282.

Hiei teaches a method for producing a fertile transgenic rice plant (Abstract and Table 1, pg 272) comprising introducing one or more genetic components (p271, "Results", last paragraph and continuing on p272), coculturing rice calli) with Agrobacterium containing the genetic component under conditions of water removal from the explants

Hiei disclose media used in cocultivation comprising either 2N-AS or N6S3-AS (Table 5, p 278, and 5<sup>th</sup> paragraph p 280), from which explants were then transferred to 2N6-CH, 2N6K-CH or N6-S3-CH, then to culture on N6-7CH (Table 5, p 278, and 5<sup>th</sup> paragraph p 280). These differences in media composition present a higher osmotic

potential in the N6-7CH medium (glucose at 20 g/L), at a later step, that in the 26-AS or N6S3-AS medium (glucose at 10 g/L), at an earlier step. It is known that water moves spontaneously from regions of lower osmotic potential to regions of higher osmotic potential (Buchanan, *op. cit.* p 1162) and further established by Applicant (specification p15). Accordingly, water has been moved from the tissue of the earlier step, decreasing the weight of the tissue, into the medium of the later step. Hiei further teaches the use of a 3 to 5 day time period for these conditions.

Accordingly, Hiei anticipates the claimed invention.

Applicant traversed, stating that the Office has not identified anywhere in Hiei a step of coculturing the Agrobacterium inoculated explant under conditions that decrease the weight of the Agrobacterium inoculated explant. To the extent that Applicant's traversal applies to the rejection above, this traversal has been addressed.

12. Claims 1, 2, 6, 7, 8, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee, P, et al, in *Agrobacterium Protocols*, K. Gartland and M Davey, eds, (1995) Humana Press, Totowa, NJ, pages 101-119.

Chee teaches a method for producing a fertile transgenic soybean plant (p 118) comprising introducing one or more genetic components (p 103, Figure 1, and p 107, all), coculturing a regenerable plant tissue with Agrobacterium containing the genetic component (p 107, item (4)) under conditions that decrease the weight of the explant (p 107, item (5)). Chee further teaches a precultured tissue (p 107, all) and use of a



moisture-removal period after inoculation with *Agrobacterium* where the time period is 4 days (p 107, item (5)).

Accordingly, Chee anticipates the claimed invention.

13. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Somerville, et al, US 5,668,292, issued September 16, 1997.

Somerville teaches a method for producing a fertile transgenic tobacco plant (column 26, lines 60-61) comprising introducing one or more genetic components (column 25 line 48, through to line 13 of column 2, and Table 3), and coculturing the explant with *Agrobacterium* containing the genetic component. Somerville further teaches soybean and corn (column 35 lines 24-28).

Somerville does not disclose conditions which decrease the weight of *Agrobacterium* inoculated explant and they do not teach adding additional water to the cocultivation medium. However, In Table 3 of Applicant's specification, when no water is added, as taught by Somerville, the explant loses weight. Therefore the method used by Somerville to produce fertile transgenic plants is inherently under conditions which would decrease the weight of the *Agrobacterium* inoculated explant. Furthermore, the weight loss of the explant with no water added is inherently not more than 50%, again as evidenced by Table 3 of Applicant's disclosure.

Accordingly, Somerville anticipates the claimed invention.

**Remarks**

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Georgia L. Helmer PhD  
Patent Examiner, Art Unit 1638  
August 2, 2002

  
PHUONG T. BUI  
PRIMARY EXAMINER  
8/2/02